IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* Kevin N. Colquitt,	§	
Plaintiffs,	§	Civil Action No. 3-06-CV-1769-M (ECF)
v.	§	
ABBOTT LABORATORIES F/K/A GUIDANT CORPORATION, *et al.*,	§	
Defendants.	§	

UNITED STATES OF AMERICA'S STATEMENT OF INTEREST ON DEFENDANTS' MOTIONS TO DISMISS

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The United States of America (United States), pursuant to 28 U.S.C. § 517, submits this Statement of Interest to respond to certain arguments set forth in the Motions to Dismiss filed by defendants Abbott Laboratories *et al.* (Abbott), Boston Scientific Corporation *et al*. (BSC), and Cordis Endovascular *et al*. (Cordis).

I. INTRODUCTION.

Although it has not intervened in this matter, the United States remains the real party in interest in this False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (FCA), case and, given that the FCA represents a critical tool the United States uses to redress fraud on the government, an incorrect application of the FCA could harm the government's efforts to combat fraud in current and future cases. The United States submits this statement of interest to address the following issues: (1) whether the Food, Drug and Cosmetic Act,

21 U.S.C. §§ 355 & 357 (FDCA), precludes actions brought under the FCA; (2) the appropriate legal standards to evaluate the FCA's falsity, materiality, and causation prongs; (3) the application of FED. R. CIV. P. 9(b) in the context of FCA cases; (4) retroactivity of the Fraud Enforcement Recovery Act (FERA) of 2009; and (5) application of the implied certification doctrine. Defendants also move to dismiss the action under the public disclosure bar of the FCA. The government takes no position at this time on that argument and submits that if the Court dismisses the matter on public disclosure grounds, it need not reach defendant's other arguments or the issues addressed in the United States's brief. If the Court addresses the issues discussed herein, the United States respectfully urges the Court to reject the defendants' arguments for the reasons stated below. The United States also asks that if the Court dismisses the case, the dismissal be without prejudice to the United States. *See United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 456 (5th Cir. 2005).

II. THE FOOD, DRUG AND COSMETIC ACT DOES NOT PRE-EMPT THE FALSE CLAIMS ACT.

Simply put, Relator alleges that the defendants in this matter caused health care providers to submit to the United States false claims for payment of vascular stenting procedures by fraudulently obtaining regulatory approvals to market biliary stents and then marketing the devices for unapproved uses in the peripheral vascular system. *See* Relator's Opp. to Defs.' Mots. to Dismiss, at 2-3. Defendants contend that their allegedly false applications to the FDA in order to secure clearance to market and sell their respective stents cannot form the basis of an FCA claim because "[t]he effect that such

false statements could or should have on FDA's clearance decision is a question of enforcement that only FDA can answer in exercising its considerable enforcement discretion." Defendants Abbott Laboratories' and Abbott Vascular Solutions, Inc.'s Mem. of Points and Authorities in Supp. of Their Mot. to Dismiss Relator's Mot. to Dismiss Relators' Third Am. Compl. (Abbott Br.), at 22. Essentially, these defendants argue that this Court should extend the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), to limit the government to only one remedy – under the FDCA – even though a company's conduct may violate numerous other federal laws. The argument is without merit; the reasoning in *Buckman* is inapplicable to FCA cases.

To start, the FCA grants the Attorney General the authority to investigate and file suits alleging the submission of false claims for money or property to the government. 31 U.S.C. § 3730(a). Only the Department of Justice, not the affected government agency, may compromise false or fraudulent claims on behalf of the government. 31 U.S.C. § 3711(b)(1). *See also Martin J. Simko Constr., Inc. v. United States*, 852 F.2d 540, 547 (Fed. Cir. 1988). Under defendants' reasoning, another government agency, the Food and Drug Administration (FDA), would first have to take some form of administrative action in order for the Department of Justice to proceed with an FCA claim. This would effectively stifle law enforcement efforts and cede control over the assertion of FCA cases from the Department of Justice to other government agencies, contrary to prevailing law. *See United States v. Southland Manag. Corp.*, 288 F.3d 665, 683-84 (5th Cir. 2002)

(recognizing the government's ability to elect remedy of its choice); *United States v. Sforza*, 326 F.3d 107, 113-14 (2d Cir. 2003) (proceeding under Federal Employees Compensation Act does not preclude recovery under FCA suit).

Moreover, the reasoning underlying the *Buckman* decision simply does not apply here. The Court in *Buckman* was concerned with the potential for private actions under state law, through allegations sounding in state tort law, to interfere with a federally-created regulatory and enforcement scheme. The Court determined that a private plaintiff could not graft traditional state law theories of tort liability on top of a federal regulatory scheme intended to be enforced exclusively by the federal government. *See Buckman*, 531 U.S. at 352-53. This matter, in contrast, involves a claim under the federal FCA to recover the money federal health insurance programs paid for procedures involving certain medical devices and is not a claim brought under the FDCA itself.[1] The FCA was enacted to redress unauthorized payments from the public fisc caused by fraud on the United States. This purpose compliments, rather than interferes with, the FDA's mandate

[1] Defendants wrongly suggest that relator's FCA suit represents an end-run around the FDA's regulatory authority. Relators brought this matter under the FCA. The FCA authorizes private individuals to bring suit on behalf of the government as a supplement to official law enforcement efforts. *See United States ex rel. Foster v. Bristol Myers Squibb Co.*, 587 F. Supp. 2d 805, 812 (E.D. Tex. 2008); *United States ex rel. Milam v. Univ. of Tex. M.D. Anderson Cancer Ctr.*, 961 F.2d 46, 49 (4th Cir. 1992) (relators bring suit as a "posse of *ad hoc* deputies to uncover and prosecute frauds against the government."). The FCA therefore enables relators to bring actions even in instances where they suffered no injury as a result of a defendant's actions because under the statute they bring suit as a partial assignee of the United States. *See Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 773 (2000). Nevertheless, the United States maintains control of the action through its right to dismiss any action it deems contrary to the interests of the United States. 31 U.S.C. § 3730(c)(2)(A).

to enforce its own regulations which, as the Supreme Court noted, it may do by: 1) seeking injunctive relief; 2) seeking civil penalties; 3) seizing products; and 4) pursuing criminal prosecutions. *See id*. at 349. The *Buckman* court clearly embraced the idea of dual enforcability when it stated that the FDA's aforementioned remedies were "[i]n addition to the general criminal proscription on making false statements to the Federal Government."[2] *Id.* at 349.

Other district courts have considered preemption in similar contexts and rejected the position that FDCA violations pre-empt FCA liability. In *United States ex rel. Franklin v. Parke-Davis*, the Court noted that although not every regulatory violation creates a cause of action under the FCA, "the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentation made to obtain a government benefit." 147 F. Supp. 2d 39, 52 (D. Mass. 2001) (emphasis in original) (denying defendant's motion to dismiss). "Thus, the failure of Congress to provide a cause of action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude an FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of 31 U.S.C. § 3729(a)."[3] *Id.* at 53. The availability of

[2] Similarly, state FCA analogs compliment, rather than conflict with, the federal government's efforts to root out fraud and abuse. *See* Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6031, 120 Stat. 7, 72 (Feb. 8, 2006) (providing for increased financial recoveries to states that enact statutes similar to the FCA).

[3] Other courts have similarly rejected arguments that regulatory remedies available to the government under existing regulatory regimes pre-empt the FCA. *See, e.g., United States ex rel. Fallon v. Accudyne Corp.*, 880 F. Supp. 636, 638 (W.D. Wis. 1995) (FCA remedies are distinct, and in addition to, statutory penalties available under Clean Water Act and Clean Air

regulatory and criminal sanctions under the FDCA therefore should not serve as a bar to recovery under the FCA.

Defendants, additionally, make much of the fact that the allegedly false statements to the FDA are not actionable because only the FDA can say whether or not those statements induced FDA clearance.[4] *See* Abbott Br., at 22. Defendants do not explain why evidence regarding the effect of defendants' alleged misstatements to the FDA could be adduced only through an FDA enforcement action rather than, for example, during the normal course of discovery in this matter.

III. LEGAL REQUIREMENTS OF AN FCA CLAIM.

A. Falsity Under the FCA

1. *Claims for Medical Devices that are Not Covered and Non-Reimbursable are False Claims.*

Regardless of the regulatory status of a device *vis à vis* the FDA, Medicare coverage is limited to medical goods and services that are "reasonable and necessary" for the diagnosis or treatment of a particular illness or injury. *See* 42 U.S.C. § 1395y(a)(1)(A) (defining scope of Medicare benefits). While a physician lawfully may use a device even though it lacks the required regulatory clearance or approval, there is no mandate that Medicare must cover the cost of the device or services involving such off-

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Act); *United States v. General Dynamics Corp.*, 19 F.3d 770, 777 (2d Cir. 1994) (Anti-Kickback Act "does not pre-empt remedies of the United States under the FCA").

[4] Defendants' argument that FDA's failure to withdraw regulatory approval indicates its acquiescence to the marketing of biliary stents for vascular purposes is disingenuous. *See* Abbott Br., at 23, n.16. Regardless of whether a company is promoting its product illegally, if a device is suitable for its approved, intended uses, then there would be no reason for the FDA to remove the device from the market entirely.

label uses. *See, e.g.*, *Goodman v. Sullivan*, 891 F.2d 449 (2d Cir. 1989) ("Medicare statute does not require coverage for all medically necessary procedures . . . ."); *Svidler v. Dept. of Health and Human Servs.*, 2004 WL 2005781, at *5 (N.D. Cal. Sept. 8, 2004) ("Plaintiff then argues that because she is allowed to prescribe off label uses, Medicare must pay for off label uses. This leap of logic is unwarranted."). The statutory standard provides the U.S. Department Health and Human Services (HHS) "wide discretion to determine whether the numerous medical services and items covered by Medicare are 'reasonable and necessary' in particular circumstances . . . [HHS] is not required to promulgate regulations or policies that, 'either by default rule or by specification, address every conceivable question' that may arise." *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 105 (D. Mass. 2009). Thus, to the extent any defendant claims that there must be a specific statute or regulation specifically governing coverage of stents in order for relator's claims to prevail, they are wrong. In addition, simply because a device has obtained FDA clearance or approval by itself "does not entitle that device to coverage." *Diapulse Corp. of Am. v. Sebelius*, No. 1:06-CV-2226, 2010 U.S. Dist. LEXIS 25003 , at *32-33 (E.D.N.Y. Jan. 21, 2010); *see Almy v. Sebelius*, Civ. A. No. RDB 08-1245, 2010 WL 3505169, at *10-11 (D. Md. Sept. 3, 2010).

Medical devices that lack clearance or approval from the FDA are considered "investigational" by federal healthcare programs and are not "reasonable and necessary." *See* 42 C.F.R. § 411.15(o) (excluding Medicare coverage for "experimental or investigational devices"). Similarly, when a medical device is cleared or approved for a

particular intended use, federal healthcare programs still may deny coverage for procedures involving that medical device, including one or more off-label uses of the device.[5] *See Svidler*, 2004 WL 2005781 (holding that medical procedure involving the use of an FDA-cleared medical device for an off-label use was experimental and not covered under Medicare). To the extent that a healthcare provider seeks reimbursement for a procedure that is ineligible for payment under a federal healthcare program, either because the program bars coverage for a particular off-label use of a device or because the program places other conditions on coverage that are not satisfied, the claim is false. Defendants do not dispute this point. *See* Mem. of Points and Authorities in Supp. of Def. Boston Scientific Corp.'s Mot. to Dismiss the Relator's Third Am. Compl. (BSC Br.), at 26; Johnson & Johnson and Cordis Corp. Mem. of Law in Supp. of Mot. to Dismiss Pursuant to FRCP 12(b)(1), 12(b)(6), and 9(b) (Cordis Br.), at 27, n. 16. Instead, they assert that biliary stents that are used off-label in the vasculature are in fact covered by Medicare.

One way in which Medicare may announce coverage determinations is to issue a National Coverage Determination (NCD). In this instance, Medicare issued an NCD regarding the treatment of peripheral vascular disease using percutaneous transluminal angioplasty, with or without placement of a stent. However, that NCD did not address the

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[5] The Ault Memo (attached as Exhibit 1-PP to the Buenafe Decl.) cited by defendant as dispositive has been superceded by subsequently enacted regulations. *See* 60 Fed. Reg. 48417, 48423 (Sept. 19, 1995); *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 75 (2nd Cir. 2006). These regulations permit, but do not require, coverage of certain investigation devices that have received an "Investigational Device Exemption" from the FDA for use prior to obtaining the necessary regulatory clearance. *See* 42 C.F.R. §§ 405.201, 405.205(a), 405.211(b).

issue of the type of stent that must be used nor the issue of whether the off-label use of defendants' devices in the peripheral vasculature is covered. *See National Coverage Determination for Percutaneous Transluminal Angioplasty* (20.7) (Joint Appendix (attached as Exhibit 1-RR to the Buenafe Decl.)). The Centers for Medicare and Medicaid Services (CMS), the agency that administers the Medicare program, instead deferred to the judgment of its local contractors, who, at their discretion, may announce coverage decisions through local coverage determinations (LCDs). Local Medicare contractors therefore had the choice to establish their own guidance regarding the conditions under which they would reimburse providers in their respective coverage regions for the off-label use of defendant's biliary devices in peripheral vascular procedures. *See* Medicare Program Integrity Manual, Ch. 13, §§ 13.1.3 and 13.4.[6]

In some instances, local Medicare contractors issued guidance that limited Medicare reimbursement for procedures involving the implantation of a vascular stent to instances where an FDA-approved stent is used for the FDA-approved indication or an FDA-approved stent is used in a different part of the peripheral vasculature and its use is supported by peer medical literature. For example, some Medicare contractors issued LCDs permitting coverage of procedures utilizing non-coronary vascular stents "only when an FDA-approved stent is: Used for the FDA-approved indications; Or, Used for the above indications supported by the peer medical literature." Trailblazer Health

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[6] Available at: http://www.cms.gov/manuals/downloads/pim83c13.pdf.

Enterprises, LLC, *Non-Coronary Vascular Stents* (4S-156AB).[7] *See, e.g.*, Wisconsin Physicians Service Insurance Corp., *Non-Coronary Vascular Stents* (CV-528) (same).[8] To the extent that an LCD provides that coverage is afforded only for procedures using non-coronary vascular devices that specifically have been approved by FDA or have support in peer-reviewed medical literature for use in the vascular system, procedures utilizing devices that fall outside the parameters established by the LCD would not be covered and claims for such procedures would be false claims. Because of the variation in coverage rules, the Medicare coverage determination for specific devices and their respective off-label uses often is a factual issue that cannot be resolved at the motion to dismiss stage.

The Medicare program is not the only federal health care provider impacted by fraudulent claims. The Veteran's Administration and the Department of Defense, among others, similarly have their own rules to determine whether program payment will be made for the off-label use of a medical devices. None of defendants' briefs address the specific reimbursement rules for federal health care payors other than Medicare.

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[7] Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=28638&lcd_version=4&basket=lcd%3A28638%3A4%3A%3Cb%3E+Non%2DCoronary+Vascular+Stents+%E2%80%93+4S%2D156AB%3C%2Fb%3E%3AMAC+%2D+Part+B%3ATrailBlazer+Health+Enterprises%7C%7C+LLC+%28402102%29%3A.

[8] Available at: http://www.cms.gov/mcd/viewlcd.asp?lcd_id=26634&lcd_version=11&show=all.

The federal military healthcare plan known as TRICARE, for example, categorically excludes coverage for "[u]nproven drugs, devices, and medical treatments or procedures." 32 C.F.R. § 199.4(g)(15). TRICARE defines "unproven" as lacking necessary FDA approval, clearance, or an investigational device exemption. 32 C.F.R. § 199.4(g)(15)(i)(A)-(B). The TRICARE provider manual states that "[i]f the device is used for a non-covered or excluded indication, benefits may not be allowed." TRICARE Manual Chap. 8 § 5.1(II)(B).[9] TRICARE therefore will not reimburse health care providers for a procedure utilizing an unproven device, and claims utilizing a non-covered device are therefore false. To the extent a third party caused the submission of a false claim under a different federal health care system, liability under the FCA may accrue.

In addition, in certain circumstances, a claim also may be rendered false under the FCA if a party engages in a fraudulent course of conduct. Thus, courts have had no difficulty concluding that when a defendant engaged in underlying criminal conduct (like bid rigging or paying kickbacks), violated a regulation, or made a false statement to procure a government benefit, the subsequent claims are false. *See, e.g., United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943) (holding that, where government contract secured by fraudulent bid rigging, "[the] fraud did not spend itself with the execution of the contract[;] [i]ts taint entered into every swollen estimate which was the basic cause for payment of every dollar paid"); *United States ex rel. Longhi v. Lithium Power Techs. Inc.*,

[9] Available at: http://www.tricare.mil/tp02/C8S5_1.PDF.

575 F.3d 458, 471-73 (5th Cir. 2009), *cert. denied*, __ U.S. __, 130 S.Ct. 2092 (2010) (invoices submitted pursuant to material false statements on grant application constitute false claims in the amount of the entire invoice submitted to the government for payment); *Scolnick v. United States*, 331 F.2d 598 (1st Cir. 1964) (imposing FCA liability based on mere cashing of check to which payee was not entitled); *Murray & Sorenson v. United States*, 207 F.2d 119, 123 (1st Cir. 1953) (secret tip that contractor could raise his bid on behalf of the corporate defendant to a price higher than would otherwise have been submitted constituted fraud); *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998) (noting that federal heath care programs require a provider to certify compliance with relevant health care laws, including the anti-kickback statute, as a condition of payment); *United States v. Inc. Village of Island Park*, 888 F. Supp. 419, 439 (E.D.N.Y. 1995) ("[T]he [FCA] is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.").

2. *The FCA Does Not Require Proof of a "Double Falsehood."*

Multiple defendants assert that a device manufacturer's promotion of a device for an off-label indication cannot support an FCA claim unless the manufacturer made fraudulent misrepresentations to a federal health care provider. *See* Abbott Br., at 26; BSC Br., at 27-28. Thus, defendants' contend that the FCA requires proof that a defendant made or caused both false statements and that a false claim resulted. However,

the assertion conflates the first two sections of the FCA, which provide independent and distinct bases for FCA liability. *Compare* 31 U.S.C. § 3729(a)(1) *with* (a)(2). Liability under section 3729(a)(1) does not require proof that a defendant made a false statement; it requires only proof that the defendant presented or caused the presentment of a false claim. *See AAA Engineering & Drafting, Inc.*, 213 F.3d 519, 531 (10th Cir. 2000) (section 3729(a)(1) only requires presentment of a false or fraudulent claim without the additional element of a false record or statement); *United States ex rel. Wilkins v. N. Am. Const. Corp.*, 173 F. Supp. 2d 601, 620-621 (S.D. Tex. 2001) ("Subsection 3729(a)(1) of the [FCA] does not contain the term 'false statement.' Rather, it requires a 'false or fraudulent claim' as the basis for liability."); *Parke-Davis*, 2003 WL 22048255, at *1 ("While § 3729(a)(2) contains a double-falsehood requirement . . ., there is no double falsehood requirement under § 3729(a)(1): One will suffice."); *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731-33 (1st Cir. 2007) (separately analyzing false statement allegations under section 3729(a)(2)).

With respect to section 3729(a)(2), defendants appear to concede that false statements to doctors regarding Medicare coding and reimbursement or FDA coverage of a device would be false statements made in order to get a false claim paid by the government, but argue that false statements to the FDA would not be. *See* Abbott Br., at 33, 35; Cordis Br., at 38. This is a distinction without a difference. Defendants seek FDA clearance and approval for their medical devices not only because they want to lawfully sell their products, but also because they know that providers are unlikely to

purchase and insurance programs are less likely to cover products that lack FDA clearance or approval. Thus the clearance or approval process is an integral step in ensuring that procedures using these devices are covered by federal programs.

In addition, the assertion that promotion of a product for an off-label use cannot amount to a "false" statement, *see* BSC Br., at 19, is equally unconvincing. As courts have long held both in the FCA context and otherwise, for a statement to be "false," it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." *W. Page Keeton, Prosser & Keeton on the Law of Torts* § 106, at 738 (5th ed. 1984). *See also United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA)*; Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); *United States ex rel. Fry v. Guidant Corp.*, 2006 WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006) (finding representation was rendered false by concealment of material information). Thus, a statement encouraging a doctor to use a device for an off-label use could well amount to a half truth and satisfy the false statement requirement of section 3729(a)(2), where, for example, the sales representative did not mention that the evidence does not support the device's efficacy for the use he or she is

promoting, the FDA has specifically concluded that the device is not effective for that use, or that there are significant, undisclosed side effects that make the device not safe for the use being promoted.

B. Medicare's Prospective Payment System Does Not Preclude Claims For Non-Covered Devices Under The FCA

In an effort to demonstrate that its alleged fraudulently obtained clearance and/or off-label marketing scheme was not material to the government's payment decisions, at least one of the defendants argues that the government's payment system is such that the claims for payment would be reimbursed nonetheless. *See* Abbott Br., at 26 n.19. In essence, Abbott contends that no false claims may result, ever, simply because CMS has made the decision to pay claims at a bundled rate. That is incorrect.

For example, courts have held that unallowable charges, even when encompassed by a fixed rate under CMS' prospective payment system, render a claim false. In *United States ex rel. Morris v. Crist*, No. C-2-97-1395, 2000 WL 432781, at *1 (S.D. Ohio Mar. 29, 2000), the relator alleged that the defendant submitted false claims to the government by failing to identify unallowable research costs on Medicare claims for payment. The court found that "the entire bill represents a claim against the United States to be paid or approved, regardless of whether or not the payment is for a flat fee." *Id.* at *5. Thus, even though Medicare's reimbursement amount, which was a prospectively determined fixed amount, was not affected by the inclusion of unallowable research charges, the inclusion of unallowable charges could render the entire claim false. *See id.* at *6. *Cf. United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 66 (D.

Mass. 2010) (false certification may be material to government's payment decision under prospective payment system); *but see United States ex rel. Kennedy v. Aventis Pharm., Inc*., No. 03 C 2750, 2008 WL 5211021, at *3 (N.D. Ill. Dec. 10, 2008). The mechanics of reimbursement, therefore, cannot be used to insulate a defendant from liability. *See United States ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 916 (7th Cir. 2005) ("If a false statement is integral to a causal chain leading to payment, it is irrelevant how the federal bureaucracy has apportioned the statements among layers of paperwork.") Moreover, all defendants concede that Medicare does not pay for all medical devices in all situations. *Cf. Stephens v. Tissue Science Labs., Inc.*, 664 F. Supp. 2d 1310, 1318 (N.D. Ga. 2009) (noting that if the primary service associated with a bundled payment is not covered, then the entire claim should be denied). The fact that such a device may be billed as part of a bundled package does not change the fact that the service may not be covered or payable. Thus, defendants' position must be rejected.

C. Liability Under The FCA Is Appropriate When A Party Causes The Submission Of A False Claim

Defendants' argument that it did not cause the submission of false claims because it was not involved in the claims process similarly fails. The FCA expressly imposes liability on individuals who knowingly cause someone else to submit a false claim for payment. 31 U.S.C. § 3729(a)(1). In interpreting the statute, courts have imposed FCA liability on defendants who caused others to submit false claims for payment, even if the party submitting the claim was unaware of its falsity. *See, e.g., United States v. Bornstein*, 423 U.S. 303 (1976) (imposing liability on subcontractor whose faulty electron

tubes were incorporated into radio kits sold to United States); *United States v. Rivera*, 55 F.3d 703, 707 (1st Cir. 1995) (imposing liability on defendant who knowingly caused third party to unwittingly submit false claims).

In cases alleging off-label marketing of a medical device, it is reasonably foreseeable that employing an army of sales representatives to promote the device for conditions that largely affect the elderly population will lead to physicians ultimately prescribing and implanting the device and seeking reimbursement from Medicare, among other payors. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 243 (3d. Cir. 2004) (knowingly assisting in causing the government to pay claims grounded in fraud actionable under FCA); *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651 PBS, 2003 WL 22048255, at *2 (D. Mass., Aug. 22, 2003) (foreseeable that non-fraudulent off-label promotion of pharmaceutical product would result in false Medicaid claims). *See also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008) (noting that a defendant is responsible for the "natural, ordinary and reasonable consequences of his conduct"). Thus, a defendant that fraudulently introduces a product to market and then uses its sales force to promote the off-label use of the product may be found to have knowingly caused health care providers to submit false claims for reimbursement.

IV. FCA COMPLAINTS NEED NOT IDENTIFY SPECIFIC INDIVIDUAL FALSE CLAIMS FOR PAYMENT.

As a general matter, a viable FCA complaint need not identify specific false claims. While it is clear that FED. R. CIV. P. 9(b) applies to complaints alleging violations

of the FCA, the rule only requires that an FCA complaint be sufficiently detailed to provide "'simple, concise, and direct' allegations of the 'circumstances constituting fraud'". *United States ex rel. Grubbs v. Kanneganti et al.*, 565 F.3d 180, 186 (5th Cir. 2009) (*quoting Williams v. WMX Techs., Inc.*, 112 F.3d 175, 178 (5th Cir. 1997)). Particularly in instances such as this one, where an FCA complaint alleges that a defendant caused false claims to be presented by a third party (i.e., through hospitals or other medical providers), the complaint may satisfy the requirements of Rule 9(b) by "alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.*, at 190; *see also United States ex rel. Duxbury v. Ortho Biotech Products*, 579 F.3d 13, 29 (1st Cir. 2009), *cert. denied*, __ U.S. __, 2010 WL 2471083 (2010) (relator satisfied elements of Rule 9(b) even though he did not identify a single false claim submitted to the government); *United States ex rel. Lusby v. Rolls Royce Corp.*, 570 F.3d 849, 854 (7th Cir. 2009) ("[w]e don't think it essential for a relator to produce the invoices (and accompanying representations) at the outset of the suit"); *United States ex rel. Lam v. Tenet Healthcare Corp.*, 481 F. Supp. 2d 689, 697 (W.D. Tex. 2007) (noting pleading standard of Rule 9(b) relaxed where the alleged fraud occurred over many years or the facts relating to the alleged fraud are within the defendant's knowledge).

In cases involving the off-label use of a pharmaceutical or medical device, a relator therefore "need not allege the details of particular claims so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" *Rost*, 507 F.3d at 732

(quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004)); *United States ex rel. Walker v. R&F Properties of Lake County, Inc.*, 433 F.3d 1349, 1360 (11th Cir. 2005), *cert. denied sub nom., R & F Properties of Lake County, Inc. v. Walker*, 549 U.S. 1027 (2006) (declining to dismiss FCA case under Rule 9(b) where relator set forth basis for allegation that defendants submitted false claims). The court in *Grubbs* explained that in FCA cases, unlike common law or securities fraud cases, specific allegations regarding the contents of an allegedly false claim were unnecessary because "a complaint need not allege that the Government relied on or was damaged by the false claim." *Grubbs*, 565 F.3d at 189; *see also United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, No. 04-186 ERIE, 2006 WL 2642518, at *7 (W.D. Pa. Sept. 13, 2006) (individual claims unnecessary at motion to dismiss stage because "the falsity of the instant claims does not turn on anything unique to any individual claim or that would be revealed from an examination of any claim"). This is especially true when, as here, the facts germane to the alleged fraud are within the knowledge of the defendant or third parties. *See United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., et al.*, 125 F.3d 899, 903 (5th Cir. 1997).

The United States does not take a position regarding whether or not the relator's complaint in this case is pleaded with sufficient particularity to support the inference that false claims were submitted to the government, or that relator has adequately alleged that one or more of the defendants engaged in conduct that caused false claims to be submitted. Similarly, the United States does not take a position as to whether or not the

complaint complies with Rule 9(b) with respect to other issues. The United States would like to set forth its opinion only that the complaint in this matter should not be dismissed based on the defendants' argument that it is deficient for failing to identify individual claims for payment. *See* Abbott Br., at 26; BSC Br., at 32; Cordis Br., at 36-38.

V. FERA APPLIES RETROACTIVELY.

Section 4(f)(1) of FERA amended section 3729(a)(2) and recodified it as section 3729(a)(1)(B) of the FCA. *See* Pub. L. No. 111-21, § 4, 123 Stat. 1617,1621 (2009). Section 3729(a)(1)(B) states that FCA liability attaches to any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim paid or approved by the Government." *Id.* FERA made this change retroactive to all cases pending as of June 7, 2008, regardless of when the conduct took place. *See United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 855 n.* (7th Cir. 2009) (noting FERA's application to conduct after May 20, 2009, except for the changes to section 3729(a)(1)(B)); *United States ex rel. Kirk v. Schindler Elevator Corp.*, 601 F.3d 94, 113 (2d. Cir. 2010) ("Because Kirk's claim was filed in March 2005, and was pending as of June 7, 2008, the potentially applicable provisions in this case are former § 3729(a)(1), establishing liability for 'knowingly present[ing], or caus[ing] to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval,' and current § 3729(a)(1)(B), establishing liability for 'knowingly mak[ing], us [ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim.'") (internal citation to FERA

omitted). Thus, to the extent the defendants suggest that the old section 3729(a)(2) applies here, they are mistaken. *See* Cordis Br., at 13-14; Abbott Br. at 27 n.20.

VI. THE APPLICATION OF THE IMPLIED CERTIFICATION DOCTRINE IN THE FIFTH CIRCUIT IS AN OPEN QUESTION.

Defendants wrongly assert that the legal concept known as implied certification "cannot form the basis of [FCA] liability." Cordis Br. at p. 35; *see also* BSC Br., at 28-30. The Court need not reach that issue because here there are express false statements made or caused by the defendants. Nevertheless, contrary to defendants' argument, the Fifth Circuit has specifically, and repeatedly, "'deferred" the question of whether "implied certifications may be claims under the [False Claims] Act." *United States ex rel. Marcy v. Rowan Cos., Inc.*, 520 F.3d 384, 389 (5th Cir. 2008) (*citing Willard v. Humana Health Plan of Texas*, 336 F.3d 375, 381-82 (5th Cir. 2003); and *United States ex rel. Stebner v. Stewart & Stephenson Servs., Inc.*, 144 Fed. Appx. 389, 394 (5th Cir. 2005) (unpublished)).

An entity submits a false or fraudulent claim within the meaning of the FCA when it misrepresents its eligibility for payment by requesting money to which it is not entitled. This can be done expressly, as in the case of the Anti-kickback Statute (AKS) where an entity expressly certifies compliance with the AKS, *see Thompson*, 125 F.3d 899, or implicitly where the mere "act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 699 (2d Cir. 2001). In either case the underlying question is whether the government could have denied payment of a claim for

goods or services that were delivered or performed in violation of a statute, rule, regulation or other precondition of payment.

Courts around the country have recognized the theory of implied certification in cases where there is a nexus between the claim for payment and regulatory compliance. *See United States ex rel. Connor v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1217-18 (10th Cir. 2008); *United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1259 (11th Cir. 2005); *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 415 (6th Cir. 2002); *Mikes*, 274 F.3d at 699-700 (2d Cir. 2001); *United States ex rel. Ebeid v. Lungwitz, et al.*, 2010 U.S. App. LEXIS 16438 (9th Cir. 2010); and *Ab-Tech Constr., Inc., v. United States*, 31 Fed. Cl. 429 (Fed. Cl. 1994), *aff'd mem.*, 57 F.3d 1084 (Fed. Cir. 1995).

Without adopting or rejecting the theory of implied certification, the Fifth Circuit has addressed regulatory non-compliance and the FCA by analyzing whether the allegation of non-compliance with a statute, regulation, rule or guideline is material to the claim for payment. *See, e.g., Rowan*, at 389. The Fifth Circuit defines materiality as a false statement that could have influenced the government's payment decision or had the potential to influence that decision. *See Longhi*, 575 F.3d at 468-69. This definition is consistent with the 2009 amendments to the FCA, which define the term "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

VII. CONCLUSION.

For the foregoing reasons, the United States respectfully asks the Court to reject the defendant's arguments addressed in this statement of interest. The United States takes no position at this time on defendants' other legal contentions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2010, a true and correct copy of this pleading was served via ECF on all persons who have entered appearances in this case.

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